

APPLICANTS: Farmer
U.S.S.N.: 09/647,695

REMARKS

Upon entry of this amendment, claims 1, 4, 8-30 and 77 are pending are pending. Claim 24 has been amended to correct a typographical error. No new matter has been added.

Claim Objection

Claim 24 has been objected to because of the misspelling of "fenofibrate." Claim 24 has been amended herein to correct this typographical error. Therefore, this objection can be withdrawn.

Claim Rejections -- 35 U.S.C. § 112

Applicants note that the rejection under 35 U.S.C. § 112, second paragraph, have been withdrawn.

Claim Rejection under 35 U.S.C. §103 (a)

Claims 1, 4, 8-40 and 77 were rejected under 35 U.S.C. §103 (a) as obvious over Paul in view of Fukushima, Bova, and Mandeville. Applicants traverse.

The claimed invention relates to a method for decreasing serum cholesterol and increasing serum HDL in a patient by administering a composition including *Bacillus coagulans* bacteria, a cholesterol-reducing agent, and a bifidogenic oligosaccharide.

The Examiner admits that Paul does not teach the method wherein *Bacillus coagulans* species are used, and states that "[a]lthough Fukushima does not teach specific species of *Bacillus*, the reference does teach the effect is achieved with the genus. Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to utilize any *Bacillus* as they were known to have the claimed effect." (See Office Action, page 7).

Contrary to the Examiner's assertions, Fukushima employs specific *Bacillus* species: *Bacillus subtilis*, *Bacillus natto* and *Bacillus megaterium*. (See Fukushima, Table 1 at p. 703, courtesy copy enclosed herewith). Therefore, Fukushima does not teach the effect is achieved with any member of the *Bacillus* genus, since only three, specific species of *Bacillus* are used, out of hundreds of *Bacillus* species.

Fukushima describes a probiotic compound containing *Bacillus subtilis*, *Bacillus natto*

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and *Bacillus megaterium*, along with four species of *Lactobacillus*, three species of *Streptococcus*, *Saccharomyces cerevisiae*, and *Candida utilis*. Fukushima does not teach or suggest the use of *Bacillus coagulans*.

The Examiner also states "it would have been obvious to one of ordinary skill in the art to use any known lactic acid bacteria because they were well known to have the beneficial effects, as claimed." (See Office Action, page 9). As discussed above, Fukushima demonstrates that a probiotic mixture containing three species of *Bacillus* bacteria, along with seven other lactic acid-producing bacteria and two species of yeast produce beneficial effects in rats fed a high-fat, high-cholesterol diet. However, thousands of strains of lactic acid-producing bacteria are known in the art, and one of ordinary skill in the art would not be motivated by the teachings of Paul in view of Fukushima to select *Bacillus coagulans*, a species whose utility in decreasing serum cholesterol and increasing serum HDL in a patient was unknown prior to the instant invention.

The remaining references, Bova and Mandeville, do not remedy the deficiency of Paul and Fukushima, since neither Bova nor Mandeville link *Bacillus coagulans* with serum cholesterol. Applicants therefore request that this rejection be withdrawn.

CONCLUSION

Based on the instant amendments and remarks, Applicants submit that this application is in condition for allowance and such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact Applicants' undersigned attorney at the telephone number indicated below.

Respectfully submitted,

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